UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,380	08/30/2001	S. Grant Mulholland	10303-2 US	7757

7590 06/13/2006

DANIEL A. MONACO, ESQ.
DRINKER BIDDLE & REATH, LLP
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,380	MULHOLLAND ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2206 and 03 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-64 and 73-79* is/are pending in the application.

4a) Of the above claim(s) *65-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-14,16-64 and 73-79* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claim 7 has been cancelled.

Claims 65-72 have been withdrawn.

Claims 1-6, 8-64 and 73-79 are pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-6, 8-10, 12-14, 16-21, 23-31, 33-41, 43-63, and 73-78 are rejected on the ground of nonstatutory obviousness-type double patenting as being

unpatentable over claims 1-21 of U.S. Patent No. 6,464,670, in view of DeSushko, 1,767,785.

As to claims 1, 3, 9, 33, 34, 35, 76, Patent '670 claims a urethral suppository formed from meltable material, comprising: a shaft tapering toward a second end; a knob extending from the second end, wherein the suppository comprises a therapeutic agent (see claim 1 of Patent '670).

However, Patent '670 does not claim that the knob is non-meltable, nor does Patent '670 claim a non-meltable reinforcement.

However, DeSushko teaches a non-meltable tube (10) with members (25) and (26), the members serving to provide compartments around the tube in which medicament is deposited and retained (see page 2, lines 16-24.) The tube (1) is flexible and preferably made of thin rubber (page 2, lines 75-77). The tube (10) with members (25 and 26) are considered the claimed non-meltable reinforcement. DeSushko also teaches a bulge (12, see fig. 2) which is non-meltable, to prevent undue removal of the device from the urethra (page 1, lines 65-70). DeSushko teaches that the bougie provides a means for retaining the bougie in the urethra, and to permit at the same time the natural urinary functions so that a more efficient bougie is provided (see page 1, lines 15-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a tube and bulge taught by DeSushko in Patent '670 because DeSushko teaches that they provide the advantage of serving as a retaining member for the medicament and to retain the device in the body, and to permit at the

same time the natural urinary functions so that a more efficient bougie is provided (see page 1, lines 15-22). One of ordinary skill in the art would recognize the advantage of providing a flexible member and a bulge as taught by DeSushko in retaining the medicament for insertion into a patient and for retaining the device to prevent undue removal, as taught by DeSushko.

As to the following claims, Patent '670 claims the following.

As to claims 3, 4, 33, 35, 36, 39, the base member is ellipsoid (see claim 3 of Patent '670).

As to claims 23 and 50, the medicament comprises antibiotics (see claim 4 of Patent '670.)

As to claim 49, the meltable portion comprises cellulose (see claim 5 of Patent '670).

As to claim 64, Patent '670 teaches that the ellipsoid member is not for insertion into the urethra (see claim 1 of Patent '670.)

As to claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Patent '670 claims the general conditions of the current claims, and discovering the dimensions as would be necessary to fit inside the body of patients is a discovery of optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

As to claim 58, Patent '670 claims the general conditions of the current claims, including use of various medicines (see claim 4) and the range in which the meltable portion melts depends on the medicine used, and discovering the range in which the meltable portion melts involves only routine skill in the art under *In re Aller.*

As to claims 62, 63, 77 and 78, discovering the optimum or workable range of time for delivering medicine requires only routine skill in the art under *In re Aller.*

As to the following dependent claims, DeSushko teaches the limitations regarding the non-meltable elements as follows.

As to claims 2 and 34, the base member (12) is shaped for handling.

As to claims 5 and 37, the base member is at (12, and including 11) and are grooved (see fig. 5).

As to claims 6 and 38, the base is roughened (i.e., see blades 11, figure 5).

As to claims 8, 40, the base is comprised of polymer (page 1, lines 75-81.)

As to claim 9, the reinforcement is considered to be embedded within the base member. (Examiner notes that this claim is directed towards a device. Although the reinforcement and the base member may be integrally formed, at the proximal end, an inner and outer portion of the material can be considered the reinforcement and base member respectively.)

As to claims 10 and 41, the reinforcement (10) projects substantially perpendicular from said base member (see fig 3).

As to claims 12 and 43, the reinforcement is in the shape of a lattice (see 25 and 26 in fig. 7, and page 2, lines 16-24.)

As to claims 13 and 44, the reinforcement (10) is formed from rubber (page 1, lines 74-77.)

As to claim 14, the second end of the reinforcement (44) is contained entirely within the meltable portion (medicine). (Examiner notes that Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to the distal end that is entirely covered with medicament.)

As to claims 18-21, 45-48, the reinforcement (10) comprises a restraint as claimed.

As to claims 26, 28, 29, 53, 55 and 56, DeSushko discloses helical grooves (11) to retain the suppository inside the urethra (page 2, lines 5, and 54-56.)

As to claims 27 and 54, the grooves are parallel to a longitudinal axis of the meltable portion (page 2, lines 15-24).

As to claim 61, the method of inserting the device in a female urethra is claimed in Patent '670, in claim 21.

As to claims 62 and 63, while Patent '670 does not claim inserting the suppository and waiting for the period of time in the ranges claimed in claim 62 and 63 in the current application, Patent '670 claims a method of using the suppository to deliver therapeutic agent to the female urinary tract (see claim 20), and discovering the optimum or workable range of time for delivering medicine requires only routine skill in the art under *In re Aller.*

2. Claims 22 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,670, in view of DeSushko, 1,767,785, as applied to claims 1 and 33, in view of Jackson et al., 4,542,020.

Patent '670 in view of DeSushko claim the invention substantially as claimed (see above), except for the meltable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the meltable portion of the suppository as claimed by Patent '670 in view of DeSushko in order to provide the advantage of uniform distribution of medication as taught by Jackson.

3. Claims 11 and 42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,670, in view of D'Augustine et al., 6,416,779.

Patent '670 claim the invention substantially as claimed in the present claim 42, except for the reinforcement being a solid rod.

Patent '670 claims a urethral suppository formed from meltable material, comprising: a shaft tapering toward a second end; a knob extending from the second

end, wherein the suppository comprises a therapeutic agent (see claim 1 of Patent '670).

D'Augustine et al. however teach a drug delivery device that can be incorporated into a coating on a suppository impregnated with liquid, drug containing solution shaped into a tampon-fitting device (col. 9, lines 62-66). D'Augustine et al. teach that the device includes a section (43) with medicine surrounding a tube (44) (col. 15, lines 10-11), and that the tube (44) is attached to a plastic loop (47) to which a string (48) may be tied for removal of the device (col. 15, lines 20-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the tube taught by D'Augustine in the device as claimed in Patent '670 because D'Augustine teaches that the tube provides the ability to attach a string for removal of the device. One of ordinary skill in the art would recognize the advantage of convenience in readily removing a drug delivery device. (The tube 44 disclosed by D'Augustine is a solid tube, see for example col. 15, line 11).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 6, 9, 10, 12-14, 18-21, 26, 28,29 and 32, are rejected under 35 U.S.C. 102(b) as being anticipated by DeSushko, 1,767,785.

As to claim 1, DeSushko teaches a non-meltable base member (13 and 14), and a non-meltable reinforcement (10 and 12), and a meltable portion (15) formed around the reinforcement and tapering from the reinforcement second end to the reinforcement first end, the first end being attached to a base member (see figure 2, disclosing that element 12 tapers towards elements 13 and 14, and thus the medicine on element 12 tapers towards elements 13 and 14), wherein the base member (13 and 14) has a width greater than the width of the meltable portion (see fig. 2.)

As to claim 2, the base member (13 and 14) is shaped for handling.

As to claim 6, the base member is considered to be roughened (see fig. 5).

As to claim 9, the reinforcement is considered to be embedded within the base member. (Examiner notes that this claim is directed towards a device. Although the reinforcement and the base member may be integrally formed, at the proximal end, an inner and outer portion of the material can be considered the reinforcement and base member respectively.)

As to claim 10, the reinforcement (10 and 12) projects substantially perpendicular from said base member (see fig 2).

As to claim 12, the reinforcement is in the shape of a lattice (see 25 and 26 in fig. 7, and page 2, lines 16-24.)

As to claim 13, the reinforcement (10) is formed from rubber (page 1, lines 74-77.)

As to claim 14, the second end of the reinforcement (i.e., distal end, see figure 2) is contained entirely within the meltable portion (medicine). (Examiner notes that

Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to the distal end that is entirely covered with medicament.)

As to claims 18-21, the reinforcement (10) comprises a restraint (see figure 7, and page 2, lines 7-24).

As to claims 26, 28, 29, DeSushko discloses a urethral suppository. DeSushko further discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.)

As to claim 32, the meltable portion is capable of melting within about 2 minutes to about 60 minutes.

5. Claims 1, 2, 8, 10, 11, 13-14, 18-21, 23 and 32, are rejected under 35 U.S.C. 102(b) as being anticipated by D'Augustine et al., 6,416,779.

As to claim 1, D'Augustine discloses a urethral suppository (col. 9, line 63) for insertion into a female urethra comprising a non-meltable base member (47); a non-meltable reinforcement (44) having a length, said length having a first end (proximal portion of 44) and a second end (distal portion of 44), said first end attached to said base member and projecting from said base member (see Figure 6); and a meltable portion (medicine, col. 15, line 24) formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end (see fig. 6, wherein the medicine is on the element 43 and the element 43 tapers towards 47, and thus the medicine tapers towards 47.)

As to claim 2, the base member (47) is shaped for handling.

As to claim 8, the base is comprised of polymer (col. 15, lines line 21.)

As to claim 10, the reinforcement (44) projects substantially perpendicular from said base member (47.)

As to claims11, the reinforcement (44) comprises a solid rod.

As to claim 13, the reinforcement (44) is formed from rubber (see col. 15, line 19.)

As to claim 14, the second end of the reinforcement (44) is contained entirely within the meltable portion (medicine). (Examiner notes that Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to include part of 44 within the medicine portion.)

As to claims 18-21, the reinforcement (44) comprises a restraint as claimed.

As to claim 23, the meltable portion comprises antifungals (see col. 20, line 39.)

As to claim 32, the meltable portion is capable of melting within about 2 minutes to about 60 minutes (see medicaments in col. 20, lines 39-43.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 16, 17, 24, 25, 30, 31, 61-64 and 73-74, 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSushko, 1,767,785.

DeSushko discloses the invention substantially as claimed (see above). More specifically, DeSushko teaches that the device is to treat urinary diseases (see page 2, lines 45-50, and 88-93.) However, DeSushko does not teach the dimensions of the suppository as claimed in claims 16, 17, 24, 25, 30, 31, and 73-74.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, DeSushko teaches the general conditions of the claims, and discovering the dimensions as would be necessary to fit inside the body of patients is a discovery of optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

As to claims 61 and 64, DeSushko also does not teach that the base member is not for insertion into the urethra. However, DeSushko teaches using the suppository in a female posterior or anterior urethra (page 2, lines 89-92) and that flaps (13 and 14) (i.e., the base member) can be folded backwardly to adhere to the flesh so as to further secure the bougie in position. It would have been obvious to one of ordinary skill in the art at the time the invention was made to secure the bougie using members 14 and 15 such that it does not insert into the urethra as necessary to deliver medicament in the posterior or anterior urethra because DeSushko teaches the general use of the adhesives on members 14 and 15 to retain the device and that the device can be used for treatment in the various parts of the body.

As to claims 76 and 79, DeSushko does not specifically teach that a segment of the reinforcement remains in the urethra and another segment remains in the bladder. However, DeSushko teaches that the device can be used for delivering medicine in the bladder (page 2, lines 45-50) and urethra (page 2, lines 88-92) when the device is in these regions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the DeSushko suppository such that a segment remains in the bladder and a segment remains in the urethra as necessary to treat affected regions because DeSushko teaches that the bladder and urethra may be treated with medicament when the device is within these affected regions.

As to claims 62, 63, 77 and 78, DeSushko also does not teach maintaining the suppository for the duration of time as claimed by Applicant for delivery of medicine. However, discovering the optimum or workable range of time for delivering medicine requires only routine skill in the art under *In re Aller*.

7. Claim 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSushko, 1,767,785, in view of Jackson et al., 4,542,020.

DeSushko discloses the invention substantially as claimed (see above), except for the meltable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.)

Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the meltable portion of the DeSushko suppository in order to provide the advantage of uniform distribution of medication as taught by Jackson.

8. Claim 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSushko, 1,767,785, in view of Sameshima et al., 6,270,789.

DeSushko discloses the invention substantially as claimed (see above), except for the medicament comprising antibiotics. However, Sameshima et al. disclose that a urethral suppository may contain antibiotics as a the medicament (col. 1, lines 16-20 and col. 2, lines 38-42.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide antibiotics as taught by Sameshima et al. as the medicament generally disclosed by DeSushko because Sameshima et al. teach that urethral suppositories may contain antibiotics, as would be desired for treating infections.

9. Claims 16, 17, 24, 25, 30, 31 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine et al., 6,416,779.

D'Augustine discloses the invention substantially as claimed (see above). More specifically, D'Augustine teaches that the suppository is for treatment of various medical conditions in various body parts (see col. 5, lines 12-22.) However, D'Augustine does

not teach the dimensions of the suppository as claimed in claims 16, 17, 24, 25, 30, 31, and 73-75.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In this case, D'Augustine teaches the general conditions of the claims (see above with under the 102 rejections). Providing the claimed dimensions as would be necessary to fit inside the vagina, rectum, pharynx, or other body parts of patients provides optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine et al., 6,416,779, in view of Jackson et al., 4,542,020.

D'Augustine et al. discloses the invention substantially as claimed (see above), except for the meltable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the meltable portion of the D'Augustine suppository in order to provide the advantage of uniform distribution of medication as taught by Jackson.

11. Claims 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Augustine, 6,416,779 DeSushko, 1,767,785.

D'Augustine discloses the invention substantially as claimed (see above), except for helical grooves being formed in the meltable portion.

DeSushko discloses a urethral suppository. DeSushko further discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.) It would have been obvious to provide helical grooves in the D'Augustine urethral suppository to provide the advantage of retaining the suppository inside the urethra as would be desirable for delivering medication to the urethra, as taught by DeSushko.

Allowable Subject Matter

12. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered.

Applicant argues on page 17 that DeSushko does not disclose a device having a meltable portion formed around the length of a reinforcement whereby the meltable portion has a diameter which tapers from the distal end of the reinforcement to the

base. This is not persuasive because the taper is disclosed by DeSushko at (12), which tapers towards the base which is at (13 and 14).

As to claims 33 and 35, Applicant argues that DeSushko does not teach a segment contained substantially entirely in the urethra and a distal segment contained substantially entirely in the bladder. With regard to claim 33, the argument concerning DeSushko is moot since rejection of claim 33 under DeSushko has been withdrawn in view of the amendments. However, Applicant's arguments concerning claim 35 is not persuasive because Applicant is claiming a device and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, DeSushko discloses the claimed structure which is capable of performing the intended use.

Applicant's arguments on page 18 regarding the rejections of claims 3 and 35 under DeSushko are moot because the rejection of claims 3 and 35 under DeSushko have been withdrawn in view of the amendments to the claims.

Applicant's argument on page 19 regarding the rejection of claims 5, 37 and 38 under DeSushko are moot because the rejections of claims 5, 37 and 38 under DeSushko has been withdrawn in view of the amendments to the claims. However the argument regarding claim 6 is not persuasive. Applicant argues that the DeSushko blade 11' does not function as a base member and is not characterized as "not for

insertion into the urethra". This is not persuasive because DeSushko discloses the claimed structure, which is capable of performing the intended use.

Applicant's argument on page 20 regarding the rejection of claim 40 under DeSushko is moot because the rejection of claim 40 under DeSushko have been withdrawn in view of the amendments to the claims. Applicant's argument concerning claim 8 is persuasive and the rejection of claim 8 under DeSushko has been withdrawn.

Applicant's argument on page 20 concerning rejection of claims 11 and 42 under DeSushko are moot because the rejections of claims 11 and 42 under DeSushko have been withdrawn in view of the amendments.

Applicant's argument on page 20 as to claim 15 is moot because the rejection of claim 15 has been withdrawn.

Applicant's argument on page 21 as to claims 53-56 are moot because the rejection of claims 53-56 under DeSushko have been withdrawn in view of the amendments to the claims. Applicant's argument regarding claims 26-29 are not persuasive however. Applicant argues that the grooves (11) in DeSushko are not formed in the meltable portion. This is not persuasive because the grooves are disclosed by DeSushko to be surrounded by medicament (see page 2, lines 7-10).

Applicant's argument on page 21 concerning claim 61 is not persuasive. Applicant argues that it would not have been obvious to secure the DeSushko bougie by adhesive such that the members would not insert into the urethra because the urethral opening in the female is located in the labia, which is surrounded by a mucous surface, making the use of adhesive flaps impractical. This is not persuasive because DeSushko

specifically teaches using the suppository in a female posterior or anterior urethra (page 2, lines 89-92) and that flaps (13 and 14) (i.e., the base member) can be folded backwardly to adhere to the flesh so as to further secure the bougie in position. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to secure the bougie using members 14 and 15 such that it does not insert into the urethra as necessary to deliver medicament in the posterior or anterior urethra because DeSushko teaches the general use of the adhesives on members 14 and 15 to retain the device and that the device can be used for treatment in the various parts of the body.

Applicant's argument on page 22 concerning claim 76 and its dependent claims are not persuasive. Applicant argues that DeSushko does not teach that the bougie extends into the bladder nor that the bougie extends past the internal urinary meatus into the bladder. This is not persuasive because DeSushko specifically teaches that the device can be used for delivering medicine in the bladder (page 2, lines 45-50) and urethra (page 2, lines 88-92) when the device is in these regions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the DeSushko suppository such that a segment remains in the bladder and a segment remains in the urethra as necessary to treat affected regions because DeSushko teaches that the bladder and urethra may be treated with medicament when the device is within these affected regions.

Applicant's arguments regarding the obviousness double patenting in terms of not referring to the claims of Patent '670 is persuasive. However, the grounds for

rejection under obviousness double patenting have now been corrected to rely only on the claims of Patent '670. Applicant's arguments regarding the substance of the obviousness double patenting however are not persuasive.

Applicant argues on pages 24 to 25 that the purpose of the tube 10 is to serve as a conduit for urine and not only to deliver medicament and that nothing in the disclosure suggests that preventing the collapse of the tube has any reinforcing effect on the bougies as a whole, and thus there is no incentive to modify the Patent '670 to introduce the tube (10). This is not persuasive because the teachings of a tube (10) for serving as a conduit for urine is itself a motivation for incorporating the tube in the Patent '670 because DeSushko teaches that the bougie provides the advantage of being more efficient because it allows the natural urinary functions while retaining the bougie in the urethra (page 2, lines 15-23).

Applicant's argument on page 25 regarding the bulge (12) is now moot because the grounds of rejection under DeSushko no longer relies on the bulge (12) as the non-meltable base.

Applicant also argues on page 26 that there is no incentive to modify the device of Patent '670 to include a tube with a bulge positioned to rest in the *fossa navicularis* to resist undue outward movement of the bougie from the urethra, as taught by DeSushko on page 2, lines 93-95, because the *fossa navicularis* is unique to the male anatomy and the Patent '670 is designed as a urethral suppository for delivering therapeutic agent to structures of the female anatomy. This is not persuasive because DeSushko also teaches that it is evident that the device may be used for treatment either with the

male or female (page 2, lines 90-93). Thus, DeSushko does suggest that the device may also be used for female treatment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Lam 6/11/06